

SUMMARY OF THE ACCREDITATION PROCESS COMMITTEE MEETING OCTOBER 9, 2002

The Accreditation Process Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on October 9, 2002 at 1:30 p.m., Eastern Daylight Time (EDT). Chairperson, Ms. Susan Wyatt of the Minnesota Department of Health led the meeting. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The purpose of the meeting was to discuss proposed language for merging or splitting distinct laboratory operations, and how these actions affect each laboratory's accreditation under NELAC.

INTRODUCTION

Ms. Wyatt called the meeting to order and took attendance.

AGENDA ITEMS

Accreditation Issues for Merged or Separated Laboratories

Ms. Wyatt noted that the primary focus of today's discussion would be accreditation issues and actions to be taken when laboratories merge or divide their operations. Of particular interest were situations where one of the laboratories has obtained NELAC accreditation and the other has not. It was noted by one of the participants that the primary issues to be answered were "what to allow" and "who will make the decisions." After describing a scenario where two certified laboratories merged, a participant noted that the issue to be addressed would be whether to allow the certifications to carryover or to require the merged laboratory to be re-certified as a new entity. It was noted that because of the numerous situations that could occur, the scenario was an indication of where NELAC needs to offer guidance to the accrediting authorities (AAs). Participants described real life situations where two separately accredited laboratories occupying the same facility share equipment although such action should not occur. Other scenarios offered by the participants included a dioxin laboratory separate from a routine analytical laboratory and a laboratory that has an air specialty that might need to select a different primary accreditation authority due to the limited scope of the initial primary accrediting authority's program.

The discussion noted that two co-located laboratories under the same ownership should not conduct analysis for the same fields of testing (FOTs). When queried as to why there would be dual accreditation under the same ownership and location, a participant responded that if the laboratories were conducting different types of work, two accreditations may be needed for the reasons previously cited. Participants also highlighted issues arising from equipment (e.g., balances, etc.) easily migrating from one laboratory to another laboratory when the two share the same physical space. One participant suggested that equipment sharing should not be allowed.

In addressing the question of whether two laboratories that have distinct business operations could share technical personnel, one response was that sharing of personnel could be allowed, however, there would need to be strict maintenance of the records of capability (i.e., training) for

all personnel. Participants also expressed the view that under these circumstances the two laboratories should not be in the same room. Also noted was the fact that an accrediting authority may have jurisdiction over only one of the merged entities, therefore, each laboratory would have to distinguish clear lines of responsibility and accountability in their quality system documents and/or application.

The following question was raised: when there are two laboratories in the same city, and the primary laboratory has accreditation, what happens when the primary laboratory wants to transfer the other laboratory's accreditation in (merge the two together)? Ms. Wyatt also raised the issue of handling quality assurance (QA) plans developed for separate laboratories that are being merged into one laboratory. When the QA plan is developed for the merged laboratory, there is also a need for new accreditation for the merged facility. A participant remarked that in that scenario, in addition to merging equipment, carrying over the entire quality system and the expertise represented by the personnel pool is key.

Laboratory Merging Fees

There was a brief discussion of accreditation fees and accreditation numbers. Ms. Wyatt pointed out that most accreditation programs are fee-based and that although fees are collected from each laboratory when they are separate entities, separate fees may not be collected if the laboratories are merged. She also noted that if two laboratories were conducting identical work, there may not be a cost recovery for the program (in terms of fees). Again, participants questioned whether two laboratories having separate accreditations and a significant overlap in their work would be required to maintain separate accreditations after merging. A participant provided an example for this discussion by noting an owner having five different laboratories with individual accreditation numbers and the problems they are experiencing in attaining a single accreditation number for the merged facilities.

Proficiency Test (PT) Sample

Issues concerning proficiency testing requirements for mobile facilities were noted. Mobile laboratories are currently required to re-apply for certification if the configuration of the facility is changed. This then requires the laboratory to perform PT analysis. Is this different from a fixed-based laboratory moving equipment from one facility to another?

A participant noted that if facility or personnel changes are not being made, then "the accrediting authority can make the decision" about PT samples. The question was raised: should mobile laboratories only be required to do 'internal QC'? Ms. Wyatt stated that she will use notes from electronic messages she received from the committee members to develop a statement on these issues and send the language to the participants for review. It was suggested that a straw poll of the Accrediting Authorities be taken. However, Ms. Wyatt noted that she had spoken to Mr. Dave Hill, who suggested raising the issue at NELAC 8i instead and allowing the AAs to comment at that time.

COMMITTEE ATTENDANCE DURING NELAC 8i

Ms. Wyatt queried the participants for other agenda items and on which participants were planning to attend NELAC 8i. No additions to the agenda were noted. In addition to Ms. Wyatt, Mr. Fred Choske, and Mr. Raymond Frederici stated they would be attending the meeting. Mr. Nicholas Macelletti will not be in attendance. The participants decided to meet as a committee some time during the conference, however, the specific day and time is to be determined.

ADJOURNMENT

The November teleconference has been cancelled and the next teleconference is scheduled for December 11, 2002, 1:30-2:30 p.m. Eastern Standard Time (EST). The participants expect to use the time to summarize the results and discussions raised at NELAC 8i.

**ACTION ITEMS
ACCREDITATION PROCESS COMMITTEE MEETING
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Item No.	Action	Date to be Completed
1.	Ms. Susan Wyatt will develop a statement addressing the performance testing issue and send it to the participants for review.	11/01/02

**PARTICIPANTS
ACCREDITATION PROCESS COMMITTEE MEETING
OCTOBER 9, 2002**

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